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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,444	04/27/2006	Jean-Philippe Houlmont	3493-0165PUS1	3437

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EXAMINER	
OLSON, ERIC	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
10/03/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/577,444	HOULMONT ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-21 and 23-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-21 and 23-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/27/06, 6/20/06, 7/25/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This application is a national stage application of PCT/FR04/02794, filed October 29, 2004, which claims priority to foreign application FR0312798, filed October 31, 2003.

Applicant's preliminary amendment submitted April 27, 2006 is acknowledged wherein claims 1-17 are cancelled and claims 18-40 are amended. Applicant's preliminary amendment submitted June 20, 2006 is acknowledged wherein claims 18-21, 23-30, and 32-36 are amended, claims 22 is cancelled, and new claims 37-40 are introduced.

Claims 18-21 and 23-40 are pending in this application and examined on the merits herein.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-21 and 23-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating inflammatory diseases, does not reasonably provide enablement for preventing inflammatory diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is drawn to a therapeutic method for treatment or prevention of inflammatory disease by administering a pharmaceutical composition. In the absence of an explicit definition in Applicant's specification, the claims are given their broadest reasonable interpretation. See MPEP 2111. Merriam-Webster's Collegiate Dictionary (reference included with PTO-892) defines "prevent" as meaning, "to deprive of power or hope of acting or succeeding," or "to keep from happening or existing." This definition is taken as representing the ordinary usage of the term "preventative". In order to deprive something of power or hope of acting or succeeding, the preventative agent must be completely effective. "Prevention" as recited in the instant claims, is interpreted to mean the complete and total blocking of all symptoms of a disorder for an indefinite period of time. Merely slowing the onset of disease or making the disease less likely would still leave it with "power or hope of acting or succeeding," and thus not qualify as prevention.

The state of the prior art: Many dermatological compositions are known in the art that can treat inflammatory conditions of the skin. However, these treatments do not qualify as a preventative treatment in the sense described above under the heading "Nature of the invention" as they are generally applied for the immediate treatment of an acute condition and are less than 100% effective.

More generally, prevention of any disorder in the sense being used herein is not a recognized clinical outcome in the art, as no treatment is perfectly effective.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: Prevention of a disease is not the same as treatment of said disease. In order to prevent a disease, as opposed to merely delaying or reducing its symptoms, a treatment must either render the subject completely resistant to said disease after a single treatment or a limited number of treatments, or else, when continued indefinitely, continue to completely suppress the occurrence of said disease. In order to practice a preventative method, one of skill in the art must know the answer to several questions in addition to the effectiveness of the therapy in short-term relief of symptoms, including:

1) What is the duration of a single course of therapy? How often must the therapy be administered to completely suppress the disease?

2) Does the subject develop tolerance to the therapy over time? Does the disease eventually progress to a point where the therapy is unable to completely suppress all symptoms? For example, will a metastatic cancer eventually adapt to overcome treatments directed to preventing it from metastasizing? Or will a case of

osteoporosis or rheumatoid arthritis ultimately progress to a point where symptoms develop regardless of which therapy is administered.

3) What are the long-term effects of the therapy? Does it cause progressive damage to the kidneys, liver, or other organs? Does the active agent accumulate in the subject's tissues? Is the minimum dose necessary to completely prevent the disease safe for long-term administration? Are there any steps that can be taken to reduce side effects?

For this reason, many therapies which are suitable for short-term relief of symptoms are not suitable for lifelong prevention of disease. For example, antibiotics, chemotherapeutics, and antiviral drugs are not normally administered to healthy subjects in order to prevent the development of infection or cancer.

The Breadth of the claims: In the absence of an explicit definition in Applicant's specification, "Prevention" as recited in the instant claims, is interpreted to mean the complete and total blocking of all symptoms of a disorder for an indefinite period of time. Any therapy which merely reduces the number or severity of symptoms, or which is effective for a period shorter than the subject's remaining lifespan, is considered to be ineffective at preventing a disorder.

The amount of direction or guidance presented: The claimed alkyl glycosides are disclosed to regulate inflammatory mechanisms. However, no guidance is given in the specification suggesting any reason to believe that administration of an alkyl glycoside can fully prevent the later occurrence of inflammation.

The presence or absence of working examples: The claimed compounds are shown to protect against inflammatory processes in cell culture, and to be non-sensitizing in an animal model of skin irritation. These working examples do not show prevention, in the broadest interpretation as described under the heading, "Nature of the Invention."

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the prevention of disease. See MPEP 2164.

The quantity of experimentation necessary: As mentioned above, the short-term usefulness of a therapy for relief of symptoms is no guarantee of its long-term usefulness for prevention of disease. Because no guidance is given for the use of the claimed therapeutic method for the long-term prevention of disease, one skilled in the art wishing to practice the invention would be unable to do so without first gathering information as to the long-term effectiveness of the therapy. In particular, one skilled in the art, in order to practice the invention for prevention of disease, would need to know whether the preventative effect remains potent over the long term.

In order to answer these questions in the absence of any existing data, one skilled in the art, in order to practice the invention, would undertake long-term animal tests, preferably over a period of years, preferably involving a relatively long-lived experimental animal such as dogs or monkeys, or a human clinical trial. Animal experiments include, along with induction of the disease state, administration of the potential pharmaceutical compound and collection and analysis of data, additional

burdens associated with compliance with animal welfare regulations, care, feeding, and other maintenance of the animals, dissection of dead animals to collect data, and disposal of dead animals after the protocol is finished. Administering the claimed compounds for a period of years to a suitable subject population is an undue amount of experimentation needed in order to practice the full range of the claimed invention. As prevention in the full sense is an extremely high bar for any clinical outcome, there is no reason to believe that the therapy would be successful, and any actual success would be a surprising and unpredictable result.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the nature of the invention and the unpredictability of the art, Applicants fail to provide information sufficient to practice the claimed invention for the prevention of inflammatory disease.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18-21, 23-26, 30, 35, 36, 39, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Houlmont et al. (Reference included with PTO-1449)

Houlmont et al. discloses pentyl and cetyl rhamnosides. (p. 364 figure 1, right column first and second paragraphs) Microemulsions were prepared with 5% of either of these compounds as cosurfactants which are especially biocompatible and nontoxic. (p. 365 right column paragraphs 3-5, p. 366 tables IV and V) These compositions can be used in cosmetic products with enhanced tolerability. (p. 366, right column paragraphs 5-10) Applying these cosmetic products to the skin inherently exerts the preventative effects claimed in instant claims 18-21, 23-28, 30, 35, 36, 39, and 40 as all subjects are potentially at risk for developing an inflammatory condition and therefore included in the target population for preventing said diseases.

Therefore Houlmont et al. anticipates the claimed invention.

Claims 18, 19, 21, 23-33, and 35-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Heiner et al. (Foreign patent publication DE19845271A1, Reference and machine translation included with PTO-892)

Heiner et al. discloses a preparation to be used in a method to protect skin against harmful oxidative processes of the skin, said composition comprising antioxidants. (p. 2 lines 55-57) The compositions are useful for treating skin again and conditions such as etythematosis, inflammation, allergic, or autoimmune conditions of the including dermatosis or photodermatosis from exposure to ultraviolet radiation. (p. 2 line 58 – p. 3 line 9) The compositions contain alkyl-glucosides which have an alkyl

group of 4-25 carbons and an average degree of polymerization of the sugar moiety of up to 2, which one skilled in the art would at once envisage as being either one or two sugar subunits. (p. 3 line 56 – p. 4 line 21) The content of monosaccharide is typically high, on the order of 40-70% of the alkyl glucosides. (p. 12, lines 37-39) Specific alkyl groups that are preferred are myristyl, cetyl, stearyl, and eicosyl. (p. 12 lines 43-45) The alkyl glucoside is used as a surfactant preferably in an amount of 0.5-15% of the weight of the dermatological composition. (p. 12 lines 53-55) Therefore Heiner et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houlmont et al. (Reference included with PTO-1449)

The disclosure of Houlmant et al. is discussed above. Houlmont et al. does not disclose a method of treating skin that is sensitive, irritated, intolerant, allergic, aged, or exhibiting other conditions as recited in claim 31.

It would have been obvious to one of ordinary skill in the art at the time of the invention to apply the cosmetic compositions of Houlmant et al to a subject whose skin is sensitive, irritated, allergic, intolerant, aged, or otherwise exhibiting a conditions that

would lead to a negative reaction to other cosmetic or dermatological compositions. One of ordinary skill in the art would have been motivated to apply these compositions because Houlmant et al. discloses that they are particularly well tolerated. One of ordinary skill in the art would reasonably expected success because determining the tolerability of a treatment as it is being administered is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 20 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heiner et al. (Foreign patent publication DE19845271A1, Reference and machine translation included with PTO-892)

The disclosure of Heiner et al. is discussed above. Heiner et al. does not disclose a method wherein the alkoxy radical comprises from 5 to 12 carbon atoms.

It would have been obvious to one of ordinary skill in the art at the time of the invention to make the compositions of Heiner et al. using an alkyl group of 5-12 carbons. One of ordinary skill in the art would have been motivated to use these alkyl groups because they are included within the broad range of 4-24 carbon atoms disclosed by Heiner et al. One of ordinary skill in the art would have reasonably expected success in doing so because the broader range of chain lengths are all disclosed as being effective in the invention.

Therefore the invention taken as a whole is *prima facie* obvious.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 1623
9/26/2008

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